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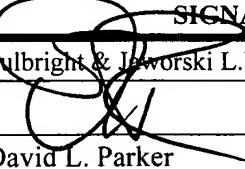
Total Number of Pages in this Submission : \_\_\_\_\_

**Application Number:** 10/812,316  
**Filing Date:** March 29, 2004  
**First Named Inventor:** Chandra U. Singh  
**Art Unit:** 1614  
**Examiner Name:** Unknown  
**Attorney Docket Number:** AZAY:006US

**ENCLOSURES (check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawings(s) _____ <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address <input type="checkbox"/> Statement under 37 CFR §3.73(b) <input type="checkbox"/> Designation of Patent Practitioners	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below)
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	<b>Remarks:</b>	

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Fulbright & Jaworski L.L.P.	Customer Number	32425
Signature			
Printed Name	David L. Parker	Reg. No.	32,165
Date	March 31, 2006		

**CERTIFICATE OF TRANSMISSION/MAILING**

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Signature			
Typed or Printed Name	David L. Parker	Date	March 31, 2006



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Chandra U. Singh  
Robert Streeper

Serial No.: 10/812,316

Filed: March 29, 2004

For: WATER SOLUBLE FORMULATIONS OF  
DIGITALIS GLYCOSIDES FOR  
TREATING CELL-PROLIFERATIVE  
AND OTHER DISEASES

Group Art Unit: 1614

Examiner: Unknown

Atty. Dkt. No.: AZAY:006US

CERTIFICATE OF MAILING  
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March 31, 2006

Date

David L. Parker

INFORMATION DISCLOSURE STATEMENT

**MS AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

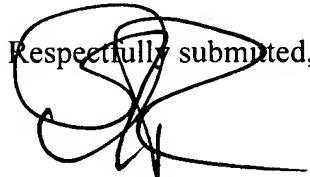
In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.



In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/AZAY:006US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,  


David L. Parker  
Reg. No. 32,165  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
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Austin, Texas 78701  
(512) 474-5201

Date: March 31, 2006

Form PTO-1449 (modified)

APR 03 2006

## List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.  
AZAY:006USSerial No.  
10/812,316

## Applicant

Chandra U. Singh  
Robert StreeperFiling Date:  
March 29, 2004Group:  
1614

## U.S. Patent Documents

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## Foreign Patent Documents

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## Other Art

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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	4,024,223	05/17/77	Noda <i>et al.</i>	514	58	04/22/75
	A2	4,228,160	10/14/80	Szejtli <i>et al.</i>	514	58	01/24/79
	A3	4,232,009	11/04/80	Hayashi <i>et al.</i>	514	58	02/22/79
	A4	4,351,846	09/28/82	Matsumoto <i>et al.</i>	514	530	05/08/81
	A5	4,353,793	10/12/82	Brunelle	208	262.5	09/25/81
	A6	4,383,992	05/17/83	Lipari	514	174	02/08/82
	A7	4,407,795	10/04/83	Nicolau <i>et al.</i>	514	58	07/16/81
	A8	4,424,209	01/03/84	Tuttle	514	58	06/21/82
	A9	4,478,811	10/23/84	Hass	423	574.1	04/13/83
	A10	4,555,504	11/26/85	Jones	514	26	03/12/84
	A11	4,565,807	01/21/86	Uekama <i>et al.</i>	514	58	07/11/83
	A12	4,727,064	02/23/88	Pitha	514	58	05/29/85
	A13	5,653,974	08/05/97	Hung <i>et al.</i>	424	85.1	11/30/94
	A14	5,824,668	10/20/98	Rubinfeld <i>et al.</i>	514	170	11/07/96
	A15	6,071,885	06/06/00	Florkiewicz	514	26	12/14/98
	A16	6,407,079	06/18/02	Muller <i>et al.</i>	514	58	10/31/88

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 00/47215	08/17/00	WIPO			

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Form PTO-1449 (modified)		Atty. Docket No. AZAY:006US	Serial No. 10/812,316
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Chandra U. Singh Robert Streeper	
		Filing Date: March 29, 2004	Group: 1614
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 2</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Bekers <i>et al.</i> , "Stabilization of mitomycins on complexation with cyclodextrin in aqueous acidic media," <i>Intl. J. of Pharmaceutics</i> , 52:239, 1989.
	C2	Brewster <i>et al.</i> , "The potential use of cyclodextrins in parenteral formulations," <i>Journal of Parenteral Science and Technology</i> , 43(5):231-240, 1989.
	C3	Chopra, "Glossary of Indian Medicinal Plants," <i>SCIR</i> , New Delhi, p175, 1956.
	C4	Dey and Bahadur, <i>Indigenous Drugs of India</i> , pp. 203-204, International Book Publishers, India, 1984.
	C5	Dymock, <i>Pharmacographia Indica</i> , 2:398, 1890.
	C6	Haux <i>et al.</i> , "Digitoxin, in non-toxic concentrations, inhibits proliferation and induces cell death in prostate cancer cell lines," <i>Z. Onkol.</i> , 32:11-16, 2000.
	C7	Haux, "Digitoxin is a potential anticancer agent for several types of cancer," <i>Med. Hypotheses</i> , 53:543-548, 1999.
	C8	Helm <i>et al.</i> , "Complex formation of beta- and gamma-cyclodextrins with digitoxin," <i>Acta Pharmaceutica Nordica</i> , 4(4):313-317, 1992.
	C9	Helm <i>et al.</i> , "Stabilization of digitalis glycosides through 2-hydroxypropyl-beta-cyclodextrin complexation in aqueous solution at pH 7.3," <i>Parmazie, Veb Verlag Volk und Gesundheit</i> , 49(7):494-496, 1994.
	C10	Huxley, <i>The New Horticultural Society Dictionary of Gardening</i> , vol.3, London, MacMillan, 1992.
	C11	Iizuka <i>et al.</i> , "Bufadienolides and a new lignan from the bulbs of <i>urgingea maritima</i> ," <i>Chem. Pharm. Bull.</i> , 49(3):282-286, 2001.
	C12	Johansson, "Cytotoxicity of digitoxin and related cardiac glycosides in human tumor cells," <i>Anticancer Drugs</i> , 12:475-483, 2001.
	C13	Kawazoe <i>et al.</i> , "Induction of apoptosis by bafalim in human tumor cells is associated with a change of intracellular concentrations of Na <sup>+</sup> ions," <i>J. Biochem.</i> , Tokyo, 126:278-286, 1999.
	C14	Kirtikar, <i>Indian Medicinal Plants</i> , pp. 800-803, International Book Distributors, India, 1987.
	C15	Manna, "Oleandrin suppresses activation of nuclear transcription factor- $\kappa$ B, activator protein-1, and c-Jun NH <sub>2</sub> -terminal kinase," <i>Cancer Res.</i> , 60(14):3838-3847, 2000.

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List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Chandra U. Singh Robert Streeper	
		Filing Date: March 29, 2004	Group: 1614
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 2</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C16	McConkey <i>et al.</i> , "Cardiac glycosides stimulate Ca <sup>2+</sup> increases and apoptosis in androgen-independent, metastatic human prostate adenocarcinoma cells," <i>Cancer Res.</i> , 60(14):3807-12, 2000.
	C17	Okada and Koizumi, "Some properties and the inclusion behavior of three positional isomers of 6(1), 6n-di-O-alpha-D-Glucosyl-cyclomaltoheptaoses (beta-cyclodextrins)," <i>Chem. Pharm. Bull.</i> , Tokyo, 46:319-323, 1998.
	C18	Pajean <i>et al.</i> , "Stabilization of liposomes with collagen," <i>International Journal of Pharmaceutics</i> , 77(1):31-40, 1991.
	C19	Pathak <i>et al.</i> , "Anvirzel™, an extract of <i>nerium oleander</i> , induces cell death in human but not murine cancer cells," <i>Anticancer Drugs</i> , 11(6):455-463, 2000.
	C20	Repke <i>et al.</i> , "The role of the NA <sup>+</sup> /K <sup>+</sup> pump in normal and cancer cell proliferation," In: <i>Biomembranes, Basic and Medical Research</i> , ed. Benga G. and Tager JM, Berlin, Springer Verlag, 161-176, 1988.
	C21	Sulkowska, "Effect of serum albumin presence on the binding constant of metronidazole to the phospholipid membranes- fluorescence study," <i>Journal of Molecular Structure</i> , 480-481:581-584, 1999.
	C22	Ueda <i>et al.</i> , "Interaction of cyclomaltononaose (delta-CD) with several drugs," <i>Drug Dev. Ind. Pharm.</i> , 25(8):951-954, 1999.
	C23	Uekama <i>et al.</i> , "Improvement of the oral bioavailability of digitalis glycosides cyclodextrin complexation," <i>J. Pharm. Sci.</i> , 72:1338-1341, 1983.
	C24	Wang <i>et al.</i> , "LC/MS/MS analyses of an oleander extract for cancer treatment," <i>Anal. Chem.</i> , 72(15):3547-3552, 2000.
	C25	Yoshida <i>et al.</i> , "Improvement of chemical instability of digitoxin in aqueous solution by complexation with beta cyclodextrin derivatives," <i>Chemical and Pharmaceutical Bulletin (Tokyo)</i> , 36(10):4075-4080, 1988.

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